

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN
PRODUCTS LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Joel Schneider,
Magistrate Judge

AGENDA FOR APRIL 24, 2019 CASE MANAGEMENT CONFERENCE

The parties hereby submit this joint agenda in advance of the April 24, 2019 Case Management Conference.

1. Plaintiffs' Leadership:

Plaintiffs' Position:

Plaintiffs have resolved the outstanding leadership issues and present the following leadership structure for the Court's consideration and approval:

Co-Leads:

Ruben Honik, Golomb & Honik
Daniel Nigh, Levin, Papantonio, Thomas, Mitchell, Rafferty, Proctor, P.A.
Adam Slater, Mazie Slater Katz & Freeman, LLC
Conlee Whiteley, Kanner & Whiteley, LLC

Executive Committee:

Ruben Honik, Golomb & Honik
Daniel Nigh, Levin, Papantonio, Thomas, Mitchell, Rafferty, Proctor, P.A.
Adam Slater, Mazie Slater Katz & Freeman, LLC
Conlee Whiteley, Kanner & Whiteley, LLC
John Davis, Slack Davis Sanger, LLP.
Marlene Goldenberg, Goldenberg Law
Behram Parekh, Kirtland & Packyard, LLP
Andres Rivero, Rivero Mestre LLP

Mikal Watts, Watts, Guerra LLP
George Williamson, Farr Law Firm
Brett Vaughn, Hollis Law Firm

Economic Reimbursement PSC:

Joseph Marchese, Bursor & Fisher, P.A.
Scott Morgan, Morgan Law Firm
John Sawin, Sawin Law Firm, Ltd.
Paul Geske, McGuire Law, P.C.
Stacey A. Burrows, George A. Barton, P.C.
Jason R. Reese, Wagner Reese, LLP
Stephanie Colella-Walsh, Stark & Stark, P.C.
Rachel Geman, Lieff, Cabraser, Heinman & Bernstein, LLP
Nicholas A. Migliaccio, Migliaccio & Rathod LLP
Gregory P. Hansel, Preti Flaherty
Peter S. St. Philip, Lowey Danenberg

Personal Injury PSC:

Jeff Gibson, Wagner Reese, LLP
Rosemarie Bogdan, Martin, Harding & Mazzotti, LLP
Steve Babin, Babin Law, LLC
Ashleigh Raso, Meshbesher & Spence
Samuel Anyan, Jr., The Cochran Firm
Annesley DeGaris, DeGaris and Rogers, LLC
Emily Jeffcott, Morgan & Morgan
Harold McCall, Wayne Wright LLP
John Boundas, Williams Kherkher
Jessica Perez, Pendley, Baudin & Coffin
Alyson Oliver, Oliver Law Group
Jon Mann, Pittman, Dutton & Hellums
David Hobbs, Fleming Nolen Jez, L.L.P.
Samuel Fisher, Wiggins, Childs, Pantazis, Fisher & Goldfarb, LLC
Roger Orlando, Orlando Law Firm

PSC Committees:

Plaintiffs will be establishing multiple PEC/PSC Committees to focus on particular areas of the litigation, including for example a TPP Committee comprised of Andres Rivero, (Rivero Mestre), Gregory Hansel (Preti Flaherty), and Peter St. Phillip (Lowey Dannenberg), and a Discovery Committee, Science Committee, Law and Briefing Committee, Time and Expense Committee, and potentially others.

Defendants' Position: At this time Defendants have no objection to the proposed leadership structure set forth above, although Defendants just received the foregoing approximately two hours before the present submission was due to the Court. As previously stated, Defendants continue to reserve the right to propose additional committees or leadership structures on the Defendants' side as may be appropriate.

2. Service on Foreign Defendants:

Plaintiffs' Position: There are at least six "foreign defendants" here: (i) Zhejiang Huahai Pharmaceutical ("ZHP") in China, (ii) Teva Pharmaceutical Industries, Limited ("Teva Ltd.") in Israel, (iii) Mylan Laboratories, Ltd. ("Mylan Ltd.") in India, (iv) Torrent Pharmaceuticals Limited ("Torrent Ltd.") in India, (v) Hetero Drugs Limited ("Hetero Ltd."), and (vi) Aurobindo Pharma Limited ("Aurobindo Ltd.") in India). The status of service efforts on each foreign defendant, and Plaintiffs' position on same, is set forth below.

ZHP. There is no longer any service issues concerning ZHP. On March 25, 2019, Jun Du, a director of ZHP, was served in the State of New Jersey in an economic reimbursement class action case, and an individual personal injury case. ZHP has agreed that service has been effectuated for all purposes in this MDL, and no further formal service on ZHP will be necessary.

Teva, Ltd. While reserving defenses (e.g., personal jurisdiction), Teva agrees it has been served through the Hague Convention with a TPP class complaint. However, Teva contends it must be served with a personal injury complaint and a consumer complaint before it is before this Court for all purposes. Plaintiffs disagree. The service of one complaint through the Hague Convention both places Teva, Ltd. under the jurisdiction of this Court for the MDL, and puts Teva Ltd. on actual notice of its involvement in this MDL. There is no constitutional or procedural requirement that 'one of each type of complaint' be served through the Hague Convention. As case in point, Plaintiff could easily amend the complaint served on Teva Ltd. to add all additional claims of every kind (personal injury and economic reimbursement) without having to re-institute Hague service. Thus, requiring Hague service of other 'types' of complaints on Teva Ltd. would be unnecessary, wasteful, and dilatory. Further, Federal Rule of Civil Procedure 4(f)(3) expressly permits this Court to approve alternative service, such as service without resort to the Hague Convention. Notably, the same procedure Plaintiffs propose here – service of any complaint through the Hague Convention discharges the need to serve other complaints through the Hague Convention – was followed in the *Benicar* litigation, and resulted in efficient and orderly discharge of formal service issues.

Mylan Ltd. Mylan's global parent company, Mylan, N.V., is a domestic entity domiciled in Pennsylvania that admittedly has been served with a class action complaint in this MDL. Mylan, N.V. nevertheless claims its Indian subsidiary, Mylan Ltd., must be served via the Hague Convention with one of each type of complaint. Plaintiffs disagree.

First, service on the parent company, Mylan, N.V., constitutes effective service on Mylan Ltd. or any other pertinent foreign subsidiary. *See, e.g., In re LDK Solar Sec. Litig.*, No. 07-cv-5182, 2008 WL 2415186, at *3-4 (N.D. Cal. June 12, 2008) (permitting service on U.S.-based parent company of foreign defendant because such service is not barred by the Hague Convention); *In re Chinese-Manufactured Drywall Prods. Liab. Litig.*, No. 09-md-2047, 2015 WL 13387769, at *3 (E.D. La. Nov. 9 2015) (approving discussion of same); *see also Nuance Commc'ns, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1239 (Fed. Cir. 2010) (stating that “federal law plainly permits service on Defendants’ domestic subsidiaries or domestic counsel”); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, No. 07-md-5944, 2008 WL 4104341, at *1 (N.D. Cal. Sept. 3, 2008) (permitting domestic service on foreign defendant’s U.S.-based subsidiary pursuant to Rule 4(f)(3)).

Second, even if this were not the case, Mylan Ltd. would need only be served with one complaint of any kind through the Hague Convention, for the reasons discussed above concerning Teva Ltd.

Torrent Ltd. Torrent is discussing a potential agreement with Plaintiffs to avoid the need to serve the foreign Torrent entity in India.

Hetero, Ltd. and Aurobindo, Ltd. Hague service has not been effectuated yet on either of these defendants. Plaintiffs believe service through the Hague Convention of any complaint is sufficient, for the reasons discussed above concerning Teva, Ltd.

Defendants’ Position: Defendants attach hereto as Exhibit A is a chart indicating which foreign Defendants have been served at least one complaint in this litigation. Defendants take the position that service of process be effectuated pursuant to Rule 4 of the Federal Rules of Civil Procedure and that foreign Defendants be served in accordance with the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters (“Hague Convention”). In an effort to compromise and to avoid unduly delaying the progress of this litigation, the foreign Defendants are willing to consider a limited waiver of their otherwise unalienable rights to proper service of process. More specifically, Defendants propose that Plaintiffs be required to formally serve each foreign Defendant at least one time with each claim asserted and therefore each type of complaint, meaning, for example, Plaintiffs would have to serve an India-based Defendant via the Hague Convention in one personal injury case, one consumer class action case, and one third party payor case. This is consistent with the overall purpose of the Hague Convention, which is “to ensure that judicial and extrajudicial documents to be served abroad shall be brought to the notice of the addressee in sufficient time.” *Id.* at 470 (citing Hague Convention, Preamble, 20 U.S.T. at 362). Once Plaintiffs have effectuated formal service of at least one complaint in each category of cases, subsequently filed complaints may be served directly upon Defendants’ counsel of record as contemplated by Rule 5(b)(1) of the Federal Rules of Civil Procedure.

With respect to Plaintiffs' position regarding purported service on specific Defendants, it should be noted that Mylan N.V. is a Dutch company which has never been served in connection with this litigation. Instead, in relation to a single consumer class action filed before this MDL was established, Mylan N.V. agreed to waive the requirements of formal service in accordance with Rule 4(d). (*See Cacaccio v. Mylan Pharmaceuticals Inc., et al.*, No. 1:19-cv-06841, Doc. No. 9 (D.N.J.)) Mylan Laboratories Ltd., an Indian-based company separate and distinct from Mylan N.V., is not even a party to the *Cacaccio* matter. Plaintiffs nonetheless insinuate that Mylan N.V.'s waiver in *Cacaccio* "constitutes effective service" on Mylan Laboratories Ltd. for all purposes and in every case that is or may at some point be transferred into this MDL. Plaintiffs, however, cite absolutely nothing in support of this extraordinary proposition. Instead, they direct the Court's attention to several unpublished district court cases from other jurisdictions addressing alternative service under Rule 4(f)(3). But Plaintiffs have never moved for leave to serve Mylan Laboratories Ltd. through alternative means, likely because they would have to "adequately support the request with affirmative evidence of the lack of judicial assistance by the host nation." *Arista Records LLC v. Media Servs. LLC*, No. 1:06-cv-15319, 2008 WL 563470, at *1 (S.D.N.Y. Feb. 25, 2008). Indeed, Plaintiffs' own case law supports the proposition that service through the Hague Convention must be attempted and thwarted before a plaintiff can resort to Rule 4(f)(3), *see In re Chinese-Manufactured Drywall Prod. Liab. Litig.*, No. 09-md-2047, 2015 WL 13387769, at *5 (E.D. La. Nov. 9, 2015), as does this Court's precedent, *see Cephalon, Inc. v. Sun Pharmaceutical Industries, Inc.*, No. 3:11-cv-5474, 2011 WL 6130416, at *5-6 (D. N.J. Dec. 11, 2011) (Wolfson, J.). Here, there is no evidence to suggest Plaintiffs have ever attempted to serve Mylan Laboratories Ltd. via the Hague Convention, to which India is a signatory, *Celgene Corp. v. Distinct Pharma*, No. 2:17-cv-5303, 2018 WL 4251848, at *3 (D.N.J. Sept. 6, 2018), so Plaintiffs' case law is inapposite. Regardless, and on a more fundamental level, Plaintiffs are simply incorrect when they suggest that service on Mylan N.V. is tantamount to service on Mylan Laboratories Ltd. "[S]ervice on a wholly owned subsidiary confers jurisdiction over the foreign parent only if the subsidiary is an alter ego or agent of the parent." *Dewey v. Volkswagen, AG*, 558 F. Supp. 2d 505, 513 (D.N.J. 2008). By the same token, service on a parent corporation does not constitute service on a subsidiary, absent piercing of the corporate veil. *I.A.M. Nat. Pension Fund v. Wakefield Industries, Inc.*, 699 F.2d 1254, 1258-59 (D.C. Cir. 1983).

3. Plaintiffs' Core Discovery Requests Upon Defendants.

Plaintiffs' Position: On April 16, 2019, Plaintiffs served narrowed Core Discovery requests on the defense, based on the instructions and guidance from the Court. Copy attached as Exhibit B. Defendants responded with a letter that opposes Plaintiffs' requests, except to the extent that Defendants have confirmed that they maintain their position that production of the ANDA, Master Drug File, and Communications with the FDA is fully sufficient to give Plaintiffs what is needed, and will not produce any other documents. Thus, despite Plaintiffs' narrowing of the requests at the Court's direction, Defendants have refused to agree to produce anything in addition to what

they originally offered – despite the Court’s instructions to the Court that they would have to do so.

In an effort to narrow the dispute, Plaintiffs asked Defendants during a meet and confer on April 22, 2019 whether Defendants will identify the pages/sections within their proposed document production (the haystack) that correspond to each request (the needles), and Defendants said they would not. Plaintiffs also asked Defendants for examples or the extent of information that is found in the Defendants’ proposed production so that Plaintiffs could at least consider the adequacy of the proposed production, and Defendants could not or would not provide that specific information either, simply stating that what we need is found in what they have already agreed to produce. Given that Defendants have not modified their original proposal in any way, Plaintiffs request production of responses to the pared down core discovery requests found in Plaintiffs’ April 16, 2019 letter.

Defendants’ Position: Prior to the March 27th initial Case Management Conference, the manufacturer Defendants agreed to produce the following documents as “core” discovery:

For API Manufacturers:

Valsartan ANDA File

The valsartan Drug Master File

Communications with the FDA relating to the valsartan and/or other ARB recalls

Supplement to the valsartan Drug Master File re: manufacturing process changes approved by FDA in the 2012-2013 timeframe

For Finished Dose Manufacturers:

The ANDA file for each involved finished dosage formulation

Communications with the FDA concerning the ARB recalls

A list of customers to whom each manufacturer sells

Consistent with Defendants’ proposal, the Court observed during the March 27th conference that “one of the first questions that [the parties] need focus on is how did this happen . . . everybody needs to focus on how this happened.” March 27, 2019 CMC Tr. at 3:11-12; 3:22-23. As the Court noted, this focus would also serve to weed out “peripheral defendants . . . who shouldn’t be here . . .” CMC Tr. at 32:23-24. The Court requested that Plaintiffs narrow their approach to reflect the different roles that each Defendant plays in the valsartan supply chain, and to ensure that the correct parties were named as Defendants. *See, e.g.,* CMC Tr. at 7:19-8:8 (suggesting Plaintiffs’ counsel consider dismissing Defendants farther down the valsartan supply chain).

Nevertheless, and notwithstanding the Court’s direction, rather than provide Defendants with specific document requests that focus on the “how” of this case and limit the burden on Defendants who do not have information regarding the valsartan API manufacturing process, Plaintiffs instead expanded their core discovery proposal to twenty-two broad categories directed to all Defendants. *See* April 2, 2019 Ltr. from

A. Slater to S. Goldberg, attached as Exhibit C. As the parties could not reach agreement as to the scope of core discovery through the meet and confer process, Defendants raised their objections to the scope of Plaintiffs' requests by letter to Magistrate Judge Schneider on April 9, 2019. *See* Exhibit D.

During the parties' conference with Magistrate Judge Schneider on April 10, he reiterated that the parties should focus on issues related to the impurities detected in valsartan by the manufacturer Defendants, and emphasized that anything outside the scope of these issues, such as sales data and litigation holds, were not within the scope of core discovery. Recognizing that core discovery should be "easily identifiable," "discrete," and "easy to retrieve," he directed Plaintiffs to "sharpen their pencils" and provide Defendants with revised requests in accordance with these guidelines.

Rather than heed the Court's guidance and "sharpen their pencils," on April 16 Plaintiffs sent Defendants a list of eleven requests that consolidated, and thus qualitatively mirrored Plaintiffs' original twenty-two requests. *See* April 16, 2019 Ltr. from A. Slater to S. Goldberg, attached as Exhibit B. However, Plaintiffs consolidated requests do not seek "easily identifiable" and "discrete" sets of documents, as the Court directed, preventing the parties from having a meaningful discussion regarding additional documents—beyond those Defendants' have already proposed—Defendants would be able to produce in a relatively short period of time. Nevertheless, in an effort to resolve this dispute, by letter of April 19 Defendants outlined the eight (of eleven) topics proposed by Plaintiffs on April 16 that are subsumed within the categories of documents that the manufacturer Defendants have offered to produce will address. *See* April 19, 2019 Ltr. from S. Goldberg to A. Slater, attached as Exhibit E.

Thereafter, during a meet and confer on April 22, Plaintiffs' leadership again refused to propose a set of "easily identifiable" documents that they believe are necessary in light of Defendants' April 19 correspondence outlining the topics that will be addressed by the manufacturer Defendants' production of documents. In light of this impasse, Defendants respectfully propose that the manufacturer Defendants move forward with their production of core discovery documents, and that the parties revisit this issue after Defendants produce such documents, which they expect to be able to complete within the next 90 days.

4. Plaintiffs' Initial Profile Forms:

Plaintiffs' Position: Plaintiffs provided defense counsel with a proposed Plaintiff Profile Form to provide the key, basic information needed by both sides and the Court to begin to understand the scope of this litigation. On April 20, 2019, Defendants provided comments and competing forms. Plaintiffs are in the process of reviewing those forms, but can say at this time the requests added by Defendants are broader than have been discussed for purposes of an initial Plaintiff Profile Form.

Plaintiffs expect to propose the use of a software program for the exchange of profile forms, and ultimately fact sheets, to which the Court would also have access.

Defendants' Position: Defendants maintain that Plaintiff Profile Forms should be completed by Plaintiffs of each type (personal injury, consumer class action class representative (including medical monitoring claims), and third party payor). Such forms should include product identification information and proof of use, as well as authorizations for the release of medical, pharmacy, and insurance records. For personal injury Plaintiffs, these forms should also include each plaintiff's medical diagnosis. For consumer class action/economic claims, these forms should also include a description of the types of damages, proof of purchase of "replacements" for valsartan. For third party payor claims, these forms should also include a description of the types of damages, proof of purchase of "replacements" for valsartan and a list of covered employers, insurers, beneficiaries and prescription drug plans

5. **ESI Protocol:**

Plaintiffs' Position: On April 8, 2019, Plaintiffs served a proposed ESI Protocol, utilizing the *Benicar* ESI Protocol, and a letter requesting core areas of ESI-related information on the Defendants. On April 22, 2019 Defendants advised that they have created a committee and will have a response in the next week. Plaintiffs are concerned as to the pace of review and resolution of the ESI Protocol, as there have been no negotiations to date, as well as Defendants' characterization of the ESI requests which are separate and apart from core discovery and necessary for Plaintiffs to intelligently approach the ESI in this case.

Defendants' Position: The parties are in the process of negotiating an ESI Protocol. Plaintiffs have proposed a protocol, which Defendants are currently reviewing. Defendants seek to agree to a protocol that is suitable given the large number and diverse array of Defendants in this litigation, who have widely varying electronic storage systems and discoverable ESI. The parties will continue to work toward an agreed protocol. Plaintiffs have included a standalone request for documents and information, in addition to their ESI protocol draft, which goes well beyond the "core discovery" contemplated by the Court.

6. **Protective Order:**

Plaintiffs' Position: During the April 10, 2019 status conference, Defendants agreed to use the *Benicar* Protective Order as the basis for an Order to be entered in this litigation, and to insert or modify provisions as necessary to address any issues inherent to this litigation. Defendants served a new proposed Protective Order late in the day on April 19, 2019. Plaintiffs are reviewing and redlining that order.

Defendants' Position: The parties have been working to develop an agreed Discovery Confidentiality Order. Pursuant to Judge Schneider's recommendation, Defendants agreed to prepare a redline of the Order entered in *In re: Benicar (Olmesartan) Prods. Liab. Litig.*, 1:15-md-02606-RBK-JS (D.N.J.) as a template. Defendants provided a redlined draft to Plaintiffs on April 19, 2019, and are awaiting Plaintiffs' response. The Parties will continue to meet and confer with Plaintiffs in order to agree upon an

order designed to accommodate the needs of this unique litigation, including in particular the need to protect Defendants' confidential business information from their competitors and downstream customers.

7. Plaintiffs' Common Benefit Order:

Plaintiffs' Position: Plaintiffs submit herewith a proposed Common Benefit Order, modeled almost entirely on the Order entered in the *Benicar* litigation. This Order does not address important related issues such as the common benefit percentage deductions to be taken from fees and expenses for the purpose of compensating the firms seeking common benefit, which will be addressed in a subsequent Order. Exhibit F.

8. Master Complaints:

Plaintiffs' Position: Plaintiffs proposed leadership currently envisions the filing of (1) an individual personal injury master complaint, (2) an economic reimbursement master class action complaint subsuming individual and third-party payor claims as subclasses, and (3) a medical monitoring class action complaint. Once leadership is appointed these decisions will be discussed and finalized. Plaintiffs request 60 days from appointment of leadership to file the master complaints.

Defendants' Position: Defendants have proposed that the current litigation would be best organized into three Master Complaints: 1) personal injury claims; 2) consumer class action claims; and 3) third-party payer claims. There is no need for a separate medical monitoring class action master complaint, as there is only one putative medical monitoring class action, which purports to represent the entire nationwide class of all valsartan users.

9. Use of State Court Discovery:

Plaintiffs' Position: Plaintiffs generally agree that state court discovery may be used in this MDL, however Plaintiffs reserve the right to address such questions on a case by case basis, depending on the circumstances. At this point, there is no active state court litigation so there is no actual issue.

Defendants' Position: Defendants are continuing to monitor the filing of state court cases, and believe it is necessary to have a better understanding of the nature and number of the state court complaints filed before coming to an agreement on the use of state case discovery in the MDL. While Defendants believe some degree of coordination would serve purposes of efficiency, Defendants do not agree at this time to a prospective, blanket agreement to incorporate any and all discovery from yet-to-be-filed state court actions.

10. Document Repository:

Plaintiffs' Position: Plaintiffs are far along in evaluating proposals from and capabilities of a number of vendors, and will make that decision within the next several weeks.

Defendants' Position: Because many Defendants are competitors and anticipate potentially producing confidential business information, it would not be appropriate for Defendants to maintain a shared repository for documents produced by Defendants.

11. Losartan/Irbesartan

Plaintiffs' Position: Plaintiffs expect that an application will likely be filed with the JPML to include these cases in this MDL at some point in the future, however, it appears that there are currently an insufficient number of cases filed in federal court to do so and the potential scope of these cases remains unknown, including potential differences as between Losartan and Irbesartan.

Defendants' Position: Because there are only two cases asserting claims based on alleged impurities found in losartan and irbesartan pending, Defendants believe that it is premature to move the JPML to include those drugs in this MDL. The JPML's Transfer Order specifically restricted the cases included in the MDL to valsartan-based litigation at this time: "We express no opinion at this time as to whether this MDL will grow to include actions involving other medications in the same class as valsartan (angiotensin II receptor blockers, or ARBs), such as the Irbesartan and losartan actions filed only in recent days." (Doc. 1 at 3 n.8). Prior to an order expanding the scope of the MDL, no discovery should take place with regard to losartan, irbesartan, or any other medication not currently covered by the Transfer Order. Defendants reserve the right to so move the JPML, if and when the number of claims involving either drug warrants their inclusion in the MDL for the purposes of efficiency.

12. Inclusion of Non-Manufacturer Defendants

Plaintiffs' Position: Plaintiffs disagree that Defendant's vaguely-defined group of drug-supply chain parties should be dismissed from this MDL at this time. Defendants appear to base their sweeping request on the assumption that only the original active pharmaceutical ingredient ("API") manufacturer has an obligation or liability vis-à-vis contaminated drugs. Not so. Each type of entity Defendants identify in their amorphous group of "wholesalers/third-party distributors, repackagers, and retailers" is independently obliged to comply with FDA current Good Manufacturing Practices ("cGMP") and/or responsible for actual or suspected contaminated drugs. *See* FDA Guidance for Industry, Q7A Good Mfg. Prac. Guidance for Active Pharmaceutical Ingredients, Part XVII.A ("All agents, brokers, traders, distributors, repackers, and relabelers should comply with GMP as defined in this guidance."); *see also* 21 U.S.C. s. 351, et seq. (the "Drug Supply Chain Security Act") (vesting all drug-supply chain parties about what to do upon realization of "illegitimate" or "suspect" product).

Additional regulations further elaborate on the obligations of other drug-supply chain parties such as wholesalers. Therefore, Plaintiffs believe it is inappropriate, and certainly premature, to dismiss any Defendant at this time.

Defendants' Position: As Defendants have previously asserted, and as the Court acknowledged at the initial Case Management Conference on March 27, 2019, certain Defendants have little, if any, involvement with, or connection, to the alleged impurities resulting in valsartan purportedly resulting from the manufacturing process. See Tr. of Mar. 27, 2019 Conference at 10:2-5 ("I'm sympathetic to that and one of the things we're going to try to do early in this case is find a method by which we can weed out people like that who really aren't necessary for this."). Defendants maintain that such parties, namely, wholesalers/third-party distributors, repackagers, and retailers, should be dismissed from any actions currently in the MDL, or should not be named as defendants in the forthcoming Master Complaints. To the extent that such parties are not excluded from the MDL, Defendants further urge that they should not be obligated to provide discovery at this time because the consumer-oriented sales-related information they may possess does not qualify as "core" discovery.

Dated: April 22, 2019

/s/ Adam M. Slater

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